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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/072,570

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Gijsbertus Johannes Van Oorschot

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EXAMINER

SULLIVAN, DANIELLE D

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,570	Applicant(s) VAN OORSCHOT ET AL.	
	Examiner DANIELLE SULLIVAN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-16, 19-24 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16, 19-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9, 11-16, 19-24 and 27-29 are pending examination. Claims 1-9 are withdrawn from examination as being drawn to a non-elected invention.

Response to Arguments

Applicant's arguments, filed 12/26/2007, with respect to the rejection(s) of claim(s) 11-28 under 35 USC §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is set forth below in view of Applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 19-21, 23, 24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632).

Applicant's Invention

Applicant claims a food product selected from the group consisting of a margarine, a dressing, a sweet, a cereal bar, a breakfast cereal and a beverage; said

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food product comprising an extract of a fermentation product formed by fermenting a substrate comprising more than 50% by weight of soy ingredients (preferable 80%) with a statins producing monascus ruber fungus; wherein the fermentation product comprises one or more statins and one or more polyphenols and has a Hue a* value less than 20; wherein said soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes; and wherein said extract is an ethanol extract or an edible oil extract (preferably more than 10% of a vegetable oil).

The fact that the fermentation product comprises statins and one or more polyphenols (comprising genistein and genistin) and has a Hue a* value less than 20 is treated as an inherent property of the soybean fermentation product (includes polyunsaturated fatty acids, phytosterols, proteins, peptides, dietary fibers and saponins) when *Monascus ruber* fungus is used. Therefore, for the purpose of examination, the fermentation product is treated as the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients with a statins producing monascus ruber fungus.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Manzoni et al. teach a method of screening *Monascus* and *Aspergillus* strains for statins production (abstract). The medium contained 3% whole or defatted soybean flour (page 254, column 1, paragraph 3). Statins could then be isolated by extraction with ethyl acetate (page, 254, column 1, paragraph 5). Once the quantitative assay

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procedure was established, fermentation experiments using strains of *Monascus* and *Aspergillus* were carried out and the whole soybean flour had a 40-41% protein and 22-24% lipid content, while the defatted flour 49-52% proteins and only 0.5%-1.5% lipid content (page 255, column 1, paragraph 2). Results show that the lipid content of the media influenced statin biosynthesis (page 257, column 1, paragraph 1). The amount of statins produced was affected by strain used and duration of fermentation (See Table 1). Manzoni et al. teach that statin result in a decrease in cholesterol (page 253, column 2, paragraph 2).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Manzoni et al. do not teach a process of making a food product comprising an extract of the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients. (However, in view of In re Auller, Lacey and Hall, 105 USPQ 233 (C.C.P.A. 1955),) I don't know this case law so you have to come and discuss it with me before using it it is normal practice to change concentration to increase the degree of results obtained. Therefore, increase in the amount of soybean flour would increase statins production.

Manzoni et al. also do not teach that the process is used in the formulation of a food product. It is for this reason that Zhang et al. is joined.

Zhang et al. teach a method of fermenting red rice with *Monascus* in order to formulate a dietary supplement or medicament for the treatment of high cholesterol in humans (column 4, lines 5-18). *Monacus ruber* is taught as a possible strain used in

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the fermentation process (column 4, lines 61-65). Zhang et al. teach that soybeans may be fermented by the process in order to obtain a nitrogen source in the food product (column 7, lines 5-20).

Manzoni et al. do not teach that the extract is an ethanol or edible oil. It is for this reason that Chaihorsky et al. is joined.

Chaihorsky et al. teach that isoflavones have been isolated from soybean plants for use as dietary supplements and include isoflavones in a glucone form, such as, genistein and genistin (column 1, lines 14-23). Typically, the isoflavones are eluted by a polar solvent such as methanol or ethanol (column 1, lines 60 and 61).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

One would have been motivated to manipulate ranges during routine experimentation to discover the optimum or workable range since Manzoni et al. provides the general range. Therefore, one would have been motivated to use the appropriate amount of soy ingredients.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al., Zhang et al. and Chaihorsky et al. to further include extracting the fermentation product with ethanol for a food product. One would have been motivated to include ethanol because it is used to concentrate isoflavones from soybeans. Therefore, using ethanol would allow for the isoflavones to be isolated from the fermentation product for incorporation into a food product.

Response to Arguments

Applicant's arguments, filed 7/18/2008, with respect to the rejection(s) of claim(s) 11-16, 19-21, 23, 24, 27 and 29 under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632) have been considered but are not found persuasive.

First, Applicant argues that a person of ordinary skill would have been dissuaded from using *Monascus ruber* to produce statins because although *M. ruber* was taught by Manzoni et al., it was not specifically mentioned again in the article. The examiner disagrees with this viewpoint. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, *M. ruber* is taught by Manzoni et al. as successively producing lovastatin. Therefore, one of ordinary skill would have been motivated to use this strain in order to obtain the statins from soybeans.

Second, Applicant argues that Zhang et al. offer no guidance as to how adequate levels of soy actives in suitable food products can be obtained. It should be noted that Zhang et al. was joined to provide motivation for formulation of a food product. Manzoni

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et al. teach the appropriate levels of soy actives obtained by the process. Zhang et al. teach a process of making a food product by fermentation in the presence of *Monascus* (column 4, lines 5-15). *Monascus ruber* is taught as a possible strain used in the fermentation process (column 4, lines 61-65). Zhang et al. teach that soybeans may be fermented by the process in order to obtain a nitrogen source in the food product (column 7, lines 5-20). Therefore, Applicant's argument have not been found persuasive.

Finally, Applicant argues that Chaihorsky et al. is silent about extractions of any fermentation products of soy. Applicant also argues that Chaihorsky et al. teach that an aqueous alkali solution is used to extract the fermentation ingredients. The Examiner disagrees with this viewpoint. Chaihorsky et al. teach that isoflavones are isolated from soy by the use of ethanol. The fact that the process uses ethanol provides motivation to use ethanol in the claimed process. Applicant argues that fermentation according to their invention converts glycosylated isoflavones into the corresponding non-glycosylated isoflavones, which are more beneficial.

Claims 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632) in further view of Zilliken (US 4,218,489).

Applicant's Invention

Applicant claims the product addressed in above 35 U.S.C. 103(a) rejection wherein the extract is an edible oil extract (preferably more than 10% of a vegetable oil).

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Manzoni et al., Zhang et al., and Chaihorsky as addressed in above 35 U.S.C. 103(a) rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Manzoni et al., Zhang et al., and Chaihorsky do not teach an extract of an edible vegetable oil containing soy ingredients. It is for this reason that Zilliken is joined.

Zilliken teach antioxidant food composition with isoflavones (abstract). Zilliken teaches that isoflavones or their extracts protect oils from oxidation (column 7, lines 46-51). Zilliken teaches a composition comprising stabilized edible oil (vegetable) and an antioxidant composition comprising 0.001-1% genistein (column 6, line 57 thru column 7 line 11).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

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It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al., Zhang et al., Chaihorsky et al. and Zilliken to further include a food product comprising soy ingredients and vegetable oil. One of ordinary skill would have been motivated to obtain a food product comprising soy ingredients (genistein) and vegetable oil because Zilliken teach that such foods are known to have reduced oxidation and thus maintain freshness.

Response to Arguments

Applicant's arguments, filed 12/26/2007, with respect to the rejection(s) of claim(s) 22, and 28 under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632) in further view of Zilliken (US 4,218,489) have been considered but are not found persuasive.

Applicant argues that the examiner has misconstrued Zilliken and that isoflavones are the antioxidants used to protect the vegetable oil from oxidation and therefore, there is no motivation to combine the teachings of Zilliken. The Examiner agrees that the teachings of Zilliken have been misconstrued, however Zilliken is relied upon to provide motivation for the soybean product being used in a food since Zilliken teaches soy food products containing vegetable oil and genistein, an isoflavone. Therefore, it would have been obvious to include vegetable oil in a soybean food product because Zilliken teaches that genistein, and isoflavone protects the oil from oxidation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
Art Unit 1616

/Johann R. Richter/

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Supervisory Patent Examiner, Art Unit 1616